



Arovella Therapeutics Limited

Appendix 4E

Preliminary Final Report

Year ended 30 June 2022

Name of entity: Arovella Therapeutics Limited
ABN: 35 090 987 250
Year ended: 30 June 2022
Previous period: 30 June 2021

Results for announcement to the market

									\$
Revenue for ordinary activities	Up	14.9%	to						295,810
Loss from ordinary activities after tax	Up	70.8%	to						(8,620,588)
Net loss for the period attributable to members	Up	70.8%	to						(8,620,588)

Net tangible assets per security

		30 June 2022	30 June 2021
		Cents	Cents
Net tangible asset backing (per share)		0.79	1.25

Explanation of results

Please refer to the review of operations and activities on pages 1 to 6 for explanation of the results.

Distributions

No dividends have been paid or declared by the Company for the current financial year. No dividends were paid for the previous financial year.

Changes in controlled entities

N/A

Other information required by Listing Rule 4.3A

N/A

Audit Status

The preliminary report is based on financial statements that are in the process of being audited.



ABN 35 090 987 250

**Preliminary Final Report
for the year ended ended 30 June
2022**

Arovella Therapeutics Limited is pleased to announce its financial results for the year ended 30 June 2022.

Highlights

- Entered into a collaborative research agreement with Imperial College London subsequent to entering into a global, exclusive licence to a novel invariant natural Killer T (iNKT) cell platform from Imperial College London
- Acquired the licence to a novel DKK1-targeting technology from MD Anderson Cancer Center
- Appointed Dr Sandhya Buchanan as VP Manufacturing and Quality and Dr Mini Bharathan as VP Development and Translational Medicine for the invariant natural killer T (iNKT) cell therapy platform
- Selected the lentivirus manufacturer and the cell therapy manufacturer to produce ALA-101
- Assembled a world class scientific advisory board to support the iNKT cell development
- Dr Debora Barton, Dr Elizabeth Stoner and Mr Gary Phillips appointed to the board of directors
- ZolpiMist - Entered into a Licence and Supply agreement with STADA Australia and launched the product; ZolpiMist received regulatory approval in Chile

Review and results of operations

The revenue for the financial year ended 30 June 2022 was \$295,810 (2021: \$257,347). The loss for the year was \$8,620,588 (2021: \$5,047,465).

The Company's net assets decreased from \$8,981,683 to \$7,616,982 at 30 June 2022 with cash reserves of \$6,070,967 (2021: \$6,717,198).

The significant events during the 2021-22 financial year were:

(i) Entered into a Collaborative Research Agreement (CRA) with Imperial College London

On 18 June 2021, Arovella announced that it has entered into a Licence Agreement for the invariant Natural Killer T (iNKT) cell therapy platform developed in the laboratory of Professor Karadimitris at Imperial College London. In preclinical studies, the iNKT cell therapy platform outperforms conventional cell therapies at initial clearance of tumour cells and promoting long-term mouse survival. Another major feature of the iNKT cell therapy platform is that it will be developed to be used off-the-shelf, as iNKT cells do not cause common side effects that confine other cell therapies to using a patient's own cells for their cancer treatment.

Under the CRA, Arovella will fund ongoing research in the laboratory of Professor Karadimitris, which will focus on creating additional intellectual property for the technology. The initial focus of the platform is for the treatment of blood cancers and the research is expected to enable Arovella to optimise the therapy and to expand into additional cancers of unmet need, creating additional intellectual property for the platform. The research agreement is for a period of two years and is extendable by mutual agreement from each party.

(ii) Assembled a world class scientific advisory board to support the iNKT cell development

In conjunction with the research agreement with Imperial College London, Arovella appointed Professor Anastasios Karadimitris, through Imperial Consultants, as Chairman of its Scientific Advisory Board (SAB) for the iNKT cell therapy program.

In addition, Arovella appointed Dr Reuben Benjamin and Dr John Maher to its Scientific Advisory Board for the iNKT cell therapy platform.

(ii) Assembled a world class scientific advisory board to support the iNKT cell development (continued)

Dr Benjamin is an internationally recognised expert in the field of cellular immunotherapies for the treatment of blood cancer. At King's College London, UK, Dr Benjamin leads the plasma cell disorder service and CAR-T cell programme. He is also a Consultant Haematologist and Honorary Senior Lecturer with an interest in multiple myeloma, stem cell transplantation and cell therapy. Dr Benjamin has an active research group at King's College London focusing on allogeneic CAR-T cells for lymphoid malignancies as well as in studying the biology of extramedullary myeloma. Dr Benjamin was the Chief Investigator of the CALM clinical trial, the first allogeneic (off-the-shelf) CAR-T cell study for relapsed adult B-cell acute lymphoblastic leukemia (B-ALL) and he was the lead author for the research paper published in Lancet in December 2020. Dr Benjamin is actively involved in offering CAR-T cell therapy for myeloma and lymphoma.

Dr Maher is an internationally recognised clinical immunologist, focused on the development of chimeric antigen receptor (CAR) cell therapies. Dr Maher played a key role in the early development of second-generation CAR technology while a visiting fellow at Memorial Sloan Kettering Cancer Center in the US, an approach that has achieved clinical impact in haematological malignancies and forms the basis for the six FDA approved CAR-T cell therapies. In 2004, Dr Maher established CAR-T cell research at King's College London, where he leads the "CAR Mechanics" group, which is focused on the development of adoptive immunotherapy using CAR engineered and gamma delta T cells. Dr Maher is also a clinically active consultant immunologist within King's Health Partners and Eastbourne Hospital. Dr Maher is the scientific founder and Chief Scientific Officer of Leucid Bio, a clinical stage cell therapy company with a pipeline of novel CAR-T cell therapies developed using its proprietary engine.

(iii) Arovella acquired the licence to a novel DKK1-targeting technology from MD Anderson Cancer Center

Arovella entered into a global, exclusive licence agreement with The University of Texas MD Anderson Cancer Center for the patent rights to a novel monoclonal antibody (mAb) developed for cancer treatment.

This is the first mAb directed against a DKK1 peptide found together with HLA-A2 on the surface of cancer cells (DKK1). DKK1 is a target that is found in many cancer types, including blood cancers and solid tumours and 40-50% of the population is HLA-A2 positive, meaning that this technology may be applicable across a wide spectrum of cancers that affect a significant proportion of the population.

Higher levels of DKK1 in cancer patients may serve as a prognostic biomarker for cancers such as Multiple Myeloma, Head and Neck Squamous Cell Carcinoma (HNSCC), Pancreatic Adenocarcinoma (PAAD), and Lung Squamous Cell Carcinoma (LUSC). Higher DKK1 production has been observed in bladder cancer and increased production of DKK1 may assist Non-small Cell Lung Carcinoma (NSCLC) cell invasion and migration. It has also been suggested that increased DKK1 levels may cause resistance to chemotherapy in cancers such as ovarian cancer.

Numerous studies have shown that multiple myeloma cells overproduce DKK1. Studies in animal models demonstrate that the DKK1-targeting technology is an excellent candidate for the treatment of multiple myeloma. It is also documented that multiple myeloma cells produce CD1d, which is recognised by invariant Natural Killer T (iNKT) cells, the core of Arovella's iNKT cell therapy platform. Arovella expects that by combining the DKK1-CAR with its iNKT cell therapy platform, it will lead to a more effective product to treat multiple myeloma and potentially other cancers. To date, the DKK1 mAb has shown promise in treating multiple myeloma when used as a single agent in mouse models. In addition, the DKK1-CAR-T successfully eliminates cancer in preclinical solid tumour models including pancreatic cancer, lung cancer and triple negative breast cancer.

More than a decade of work has gone into the production and testing of the DKK1 mAb. Professor Qing Yi, now at Houston Methodist, developed the technology during his time at MD Anderson as a tenured Professor of Medicine. At Houston Methodist, Professor Yi has continued the research, assessing the potential of the DKK1-CAR. Professor Yi was recruited to Houston Methodist in 2018 through a US\$6m Cancer Prevention and Research Institute of Texas (CPRIT) award.

(iv) Arovella appointed Dr Sandhya Buchanan as VP of Manufacturing and Quality Dr Mini Bharathan as the VP of Development and Translational Medicine for the invariant natural killer T (iNKT) cell therapy platform

Arovella appointed Dr Sandhya Buchanan as its VP of Manufacturing and Quality for its iNKT cell therapy platform. Dr Buchanan's role will encompass leading the technology transfer, manufacturing, and quality aspects for production of the cell therapy for clinical development stages. Dr Buchanan joined Arovella from Atara Biotherapeutics, a biotechnology company pioneering off-the-shelf cell therapies for treating cancer and autoimmune disease.

During her time at Atara Biotherapeutics, Dr Buchanan served as the chemistry manufacturing and control technical lead for autologous CAR-T programs and head of Viral Vector Development; managing both internal and external collaborations. Prior to Atara Biotherapeutics, Dr Buchanan held senior roles at Torque Therapeutics (now Repertoire Immune Medicines), FujiFilm Diosynth Biotechnologies, Penn Medicine, a world-renowned academic medical center in Philadelphia, and Novartis.

Dr Buchanan has more than 20 years' experience working in cell & gene therapy and vaccine development. Dr Buchanan has a PhD in Pharmaceutical Sciences from the University of Colorado Health Sciences Center and has co-authored a number of peer reviewed scientific articles and patents.

Arovella also appointed Dr Mini Bharathan as its VP of Development and Translational Medicine for its iNKT cell therapy platform. Dr Bharathan's role will encompass leading the nonclinical studies for its CD19 and DKK1 targeting products, to advance each therapy into clinical studies.

Dr Bharathan joins Arovella from Collectis, a biotechnology company that is using its pioneering gene-editing platform to develop allogenic therapies, which entails collecting the starting material for the cell therapy from a healthy donor as opposed to the patient suffering from the cancer.

During her time at Collectis, Dr Bharathan served as the Director of Translational Medicine and Clinical Development where she coordinated the development programs for key products, recommended patient stratification and biomarker strategies and oversaw the development and validation of novel clinical stage assay methodologies, patient selection markers and biomarkers for multiple global allogenic CAR-T clinical trials. Dr Bharathan also held senior roles at Celgene, Celularity and Immatics, all focused on the development of cell therapies.

Dr Bharathan has more than 15 years' experience in the field of immunology with more than 12 years focused on the development of cell therapies. Dr Bharathan is a Doctor of Veterinary Medicine and holds a PhD in immunology from Virginia Tech where she was the recipient of the Sigma Xi Outstanding Ph.D. Research Award. Dr Bharathan has co-authored numerous research articles and patents.

(v) Arovella selected the plasmid, lentivirus and cell therapy manufacturer to produce ALA-101

During the period, Arovella screened numerous contract manufacturing organisations (CMOs) to produce two important components to produce the therapy, plasmid DNA and lentiviral vector. The CMO was selected and they initiated work during January 2022, which is continuing.

Arovella agreed the commercial terms for the initial Manufacturing Services Agreement for its first investigative CAR19-iNKT cell therapy candidate (ALA-101) with Q-Gen Cell Therapeutics (Q-Gen), the cell therapy manufacturing arm of the QIMR Berghofer Medical Research Institute (QIMR Berghofer). Streamlining manufacturing is a critical step to initiate clinical trials for Arovella's lead product, ALA-101 to treat CD19-producing leukemias and lymphomas.

(v) Arovella selected the plasmid, lentivirus and cell therapy manufacturer to produce ALA-101 (continued)

Q-Gen is at the forefront of manufacturing immunotherapies and cell therapies. Established in 2002 to support clinical translation and discoveries by the Institute's researchers, the facility now manufactures for academic and biopharmaceutical partners nationally and internationally. Q-Gen is accredited by Australia's Therapeutic Goods Administration as a Good Manufacturing Practice (GMP) facility. The facility can produce cellular immunotherapies for patients in Australia, Asia, the United States and Europe. Q-Gen has successfully produced autologous and allogenic cell therapy products for clinical trials.

The Services Agreement is anticipated to be followed by a proposed Master Manufacturing Services Agreement. The proposed Services Agreement allowed Arovella to begin to work with Q-Gen to manufacture the product for clinical trials. IP created under the services agreement will vest with Arovella, unless created solely by QIMR Berghofer, who will retain such IP.

(vi) Appointed Dr Debora Barton, Dr Elizabeth Stoner and Mr Gary Phillips to the board of directors

Over the course of the year and following the acquisition of the cell therapy platform, Arovella appointed Dr Debora Barton, MD, Dr Elizabeth Stoner and Mr Gary Phillips as independent Non-Executive Directors. Also, during the year, Dr Stoner assumed the role as interim Chairperson, upon Mr Paul Hopper stepping down from his role as Non-Executive Chairman. The Company is continuing its search for a replacement.

Dr Debora Barton

Dr Barton has over 20 years' experience in the field of oncology. After practicing oncology as a physician and clinical trial investigator, she spent five years at Novartis and five years at Celgene in roles of increasing responsibilities in Medical Affairs and Clinical Development. Dr Barton has extensive experience working with cell therapy products, formerly as the Senior Vice President, Clinical and Head of Safety, of the clinical stage company, Iovance, who are developing T cell therapies for cancer treatment and formerly as Chief Medical Officer of Carisma Therapeutics, who are developing CAR-Macrophage therapies. Dr Barton is currently the Chief Medical Officer of TScan Therapeutics, a pre-clinical stage biopharmaceutical company, developing life-changing T cell therapies for patients by unleashing the untapped potential of the human immune system.

Dr Barton is a member of the Manhattan Board of Directors for the American Cancer Society and is also a member of the Medical Advisory Board of the Tigerlily Foundation, a national breast cancer foundation providing education, awareness, advocacy and hands-on support to young women before, during and after breast cancer.

Dr Elizabeth Stoner

Dr Stoner, based in Boston, has over 30 years' experience in the life-sciences sector, spanning early-stage research, drug development and venture investing. She is currently Executive Partner at MPM Capital, a leading US healthcare investment firm, with over two decades of experience founding and investing in life-sciences companies that seek to translate scientific innovations into cures for major diseases. In her role, Dr Stoner serves as a clinical advisor to several of MPM Capital's portfolio companies, including AlloVir, and Rhythm Pharmaceuticals. Additionally, Dr Stoner served as the interim CEO of the cell therapy biotechnology company, Semma Therapeutics, which was acquired by Vertex in 2019 for US\$950 million.

Prior to joining MPM Capital, Dr Stoner was Senior Vice President of Global Clinical Development Operations at Merck Research Laboratories where she was responsible for its clinical development activities in more than 40 countries. While at Merck, she also oversaw the clinical development activities of its Japanese subsidiary and played a leading role in Merck/Schering Plough Joint Venture's development of Vytorin and Zetia, blockbuster cholesterol lowering drugs. Previously, she led the 5-alpha reductase clinical development program, establishing Merck as a leader in the field of prostate disease.

Dr Stoner currently serves on the board of Triplett Therapeutics. She is also a member of the Albert Einstein College of Medicine Board of Governors, and the Weill Cornell Medical College Clinical and Translational Science Center External Advisory Board.

Dr Stoner received her M.D. from the Albert Einstein College of Medicine and prior to joining the biopharma industry, she was an Assistant Professor of Paediatrics at Cornell University Medical College.

(vi) Appointed Dr Debora Barton, Dr Elizabeth Stoner and Mr Gary Phillips to the board of directors (continued)

Mr Gary Phillips

Mr Phillips has more than 30 years of operational management experience in the pharmaceutical and healthcare industry in Europe, Asia and Australia. He is currently the CEO and Managing Director of the ASX-listed company, Pharmaxis (ASX:PXS). Following his appointment as Pharmaxis CEO, Mr Phillips has overseen a company restructure focused on building value, forging new partnerships, and fostering the development of the Pharmaxis product pipeline.

Prior to joining Pharmaxis, he was the CEO at Ciba Geigy in Hungary (Merged to form Novartis in 1996) where he led the successful launch of a portfolio of new products. Mr Phillips was Novartis' area manager covering nine countries across Asia Pacific before joining Novartis Australia as Group Company Head and Chief Executive Officer of its Pharmaceutical Division, successfully launching leading oncology and ophthalmology products.

Mr Phillips holds a Bachelor of Pharmacy Honours degree from Nottingham University in the U.K. and an MBA from Henley Management College, UK. Mr Phillips is also a Graduate of the Australian Institute of Company Directors (GAICD).

(vii) ZolpiMist - Entered into a Licence and Supply Agreement with STADA Australia and launched the product; ZolpiMist received regulatory approval in Chile

STADA Australia partnership and commercial launch

Arovella entered into an exclusive License and Distribution Agreement for ZolpiMist (zolpidem tartrate, a product indicated for the short-term treatment of insomnia in adults) in Australia with STADA Pharmaceuticals Australia Pty Ltd, a member of the global, German-based STADA Group. Arovella obtained approval from the Therapeutic Goods Administration (TGA) for ZolpiMist as announced 29 July 2020 and continues to work closely with its other licensee, Teva. Arovella will submit a further application to the TGA for a modification to the current spray unit, incorporating in the application a more economical, elegant, and user-friendly child resistant lock (CRL). It is anticipated that the new CRL will be implemented from the second batch of product produced for STADA onward.

Key terms of the Agreement:

- i. The Agreement is a perpetual, exclusive Licence for ZolpiMist® for Australia;
- ii. STADA has the option to distribute the product in New Zealand;
- iii. Arovella received an upfront fee of \$170,000 and are entitled to a milestone payment of \$40,000;
- iv. The milestone payment is linked to the approval of the enhanced CRL;
- v. Arovella will receive a 10% royalty based on net sales of the enhanced product;
- vi. Arovella to manufacture and supply the product at agreed supply prices;
- vii. STADA is responsible for commercialisation of the product in Australia;
- viii. The agreement is subject to standard termination clauses.

STADA expected sales to commence in Q3 CY2022. It was pleasing that STADA Australia initiated its commercial launch for ZolpiMist earlier than expected, in Q2 CY2022. STADA also has an option to commercialise the product throughout New Zealand and is considering expanding its footprint across additional territories.

ZolpiMist approval in Chile

The Ministry of Health, Chile, approved the registration of ZolpiMist by Teva Pharmaceuticals for the treatment of short-term insomnia in adults.

Teva Pharmaceuticals submitted a Marketing Authorisation Application (MAA) with the new supplemental API supplier and the Australian final product manufacturer to the Chilean authority for ZolpiMist in May 2021. Approval was granted significantly sooner than the expected date of April 2022.

The benefits of the Chile approval are:

- ZolpiMist can be commercialised and supplied within Chile;
- It demonstrates compliance with international Good Manufacturing Practice and an ability to obtain regulatory approvals with partners.

(viii) Additional OroMist Updates

Received notice from the United States Patent Office that the anagrelide patent would proceed to grant

The US Patent and Trademark Office (USPTO) accepted Arovella's patent application covering anagrelide and the patent will proceed to grant.

The USPTO will grant Arovella's Application No. 15/538,326 titled "Use of Anagrelide for Treating Cancer". The patent has an expiry of December 2035 and it adds to the granted patents in Europe, Japan and Australia.

Anagrelide is being developed for the treatment of metastatic disease in patients who have certain solid tumour cancers. Clinical experience has shown that increased platelet numbers associated with several solid tumour cancers decreases progression-free life expectancy. Anagrelide not only advantageously lowers blood platelets, but it has also been shown to inhibit cancer cell movement towards platelet-producing cells, megakaryocytes, principally found in the bone marrow but also the lung, two likely sites of metastases.

Arovella is actively seeking to find co-development partners to fund ongoing research or to out-licence the anagrelide intellectual property to entities focused on development of cancer therapies, where increased platelets play a role in the progression of the disease. This includes a number of cancer types, including melanoma, mesothelioma, ovarian, vulvar, cervical, renal cell, lung, glioblastoma, pancreatic, endometrial and colorectal cancer.

MTPK termination for ZolpiMist

Mitsubishi Tanabe Pharma Korea (MTPK) indicated its intention not to proceed with the License and Supply Agreement for ZolpiMist. MTPK cited challenges with its regulatory body, the Ministry of Food and Drug Safety (MFDS). Arovella agreed to terminate the Agreement and the Company notes that there is no immediate financial impact as a result of the termination. Arovella will continue to focus on its partnership with TEVA, and look to secure additional partners for the ASEAN region and other territories.

Strides Termination Sumatriptan

Strides Pharma Global Pte Ltd (Strides) indicated its intention to cease the Development, Licence and Supply Agreement (Agreement), citing a change in market conditions, which have made the project unviable from their perspective as their primary reason to cease the Agreement. Arovella agreed to terminate the Agreement under the relevant provisions contained in the Agreement and the Company notes that was no cost impact to Arovella or immediate impact on revenue streams.

In conjunction with the termination, Arovella reviewed the operations of the business and restructured the reformulation group to match the reduced requirements for reformulation project work.

(ix) Completion of \$6.57m capital raising

Arovella completed a Placement, raising funds from institutional and sophisticated investors for a \$4.57 million Placement of 120,230,220 new fully paid ordinary shares (New Shares) in the Company at a price of \$0.038 per share (Placement). The price of the Placement was set at a 2.5% discount to the last traded market price.

The Placement received very strong support from institutional and sophisticated investors and includes cornerstone participation by specialist life sciences institutional investor, Merchant who subscribed for \$3 million of the Placement. The Placement was followed by a Share Purchase Plan (SPP) for eligible existing shareholders at the same offer price as the Placement. The SPP was closed early due to high demand, raising an additional \$2 million.

Funds raised in the Placement and SPP are being used to progress development of the Company's iNKT cell therapy platform and DKK1-peptide targeting monoclonal antibody licensed from the world-renowned MD Anderson Cancer Center.

Arovella Therapeutics Limited
Statement of Profit or Loss and Other Comprehensive Income
For the year ended 30 June 2022

	Notes	2022 \$	2021 \$
Revenue from contracts with customers	2(a)	295,810	257,347
Cost of sales		(207,056)	(222,750)
Gross profit		88,754	34,597
Other income		-	906,670
Interest income	2(b)(i)	3,845	6,542
Depreciation and amortisation expense	2(b)(iii)	(551,488)	(652,176)
Employee benefits expenses		(1,322,038)	(1,306,230)
Finance costs	2(b)(iv)	(194,720)	(33,294)
Impairment of intangible assets	5	(833,271)	(1,239,467)
Other expenses	2(b)(v)	(3,215,555)	(2,056,308)
Research cost		(2,596,115)	(707,799)
Loss before income tax		(8,620,588)	(5,047,465)
Loss before income tax from continuing operations		(8,620,588)	(5,047,465)
Income tax expense		-	-
Loss for the year		(8,620,588)	(5,047,465)
Other comprehensive income			
Total comprehensive loss for the year		(8,620,588)	(5,047,465)
		Cents	Cents
Loss per share for loss attributable to the ordinary equity holders of the Company:			
Basic and diluted loss per share	3(a)	(1.57)	(1.52)

The above Statement of Profit or Loss and Other Comprehensive Income should be read in conjunction with the accompanying notes.

Arovella Therapeutics Limited
Statement of Financial Position
As at 30 June 2022

	Notes	2022 \$	2021 \$
ASSETS			
Current assets			
Cash and cash equivalents		6,070,967	6,717,198
Trade and other receivables	4	36,290	533,637
Other current assets		480,339	92,309
Total current assets		<u>6,587,596</u>	<u>7,343,144</u>
Non-current assets			
Property, plant and equipment		266,061	380,903
Right-of-use assets		105,412	52,037
Intangible assets	5	2,253,271	2,911,206
Total non-current assets		<u>2,624,744</u>	<u>3,344,146</u>
Total assets		<u>9,212,340</u>	<u>10,687,290</u>
LIABILITIES			
Current liabilities			
Trade and other payables	6	815,525	1,226,899
Contract liabilities	2(a)	341,684	200,000
Provisions		284,045	191,565
Borrowings		1,122	5,721
Lease liabilities		66,228	70,772
Total current liabilities		<u>1,508,604</u>	<u>1,694,957</u>
Non-current liabilities			
Provisions		9,300	7,908
Borrowings		-	2,742
Lease liabilities		77,454	-
Total non-current liabilities		<u>86,754</u>	<u>10,650</u>
Total liabilities		<u>1,595,358</u>	<u>1,705,607</u>
Net assets		<u>7,616,982</u>	<u>8,981,683</u>
EQUITY			
Issued capital	7	83,536,397	77,003,347
Reserves		1,105,098	450,686
Accumulated losses		(77,024,513)	(68,472,350)
Total equity		<u>7,616,982</u>	<u>8,981,683</u>

The above Statement of Financial Position should be read in conjunction with the accompanying notes.

Arovella Therapeutics Limited
Statement of Changes in Equity
For the year ended 30 June 2022

Attributable to owners of Arovella Therapeutics Limited					
Notes	Issued capital \$	Accumulated losses \$	Share-based payment reserve \$	Minority interest acquisition reserve \$	Total equity \$
Balance at 1 July 2020	67,385,981	(64,880,540)	225,712	1,404,267	4,135,420
Loss for the year	-	(5,047,465)	-	-	(5,047,465)
Total comprehensive loss for the period	-	(5,047,465)	-	-	(5,047,465)
Shares issued during the period	10,580,879	-	-	-	10,580,879
Share issue costs	(963,513)	-	-	-	(963,513)
Issue of options to broker	-	-	239,025	-	239,025
Options lapsed during the period	-	51,388	(51,388)	-	-
Equity settled share-based payments	-	-	37,337	-	37,337
Reclassification of reserve to accumulated losses	-	1,404,267	-	(1,404,267)	-
Balance at 30 June 2021	77,003,347	(68,472,350)	450,686	-	8,981,683
	Issued capital \$	Accumulated losses \$	Share-based payment reserve \$	Minority interest acquisition reserve \$	Total equity \$
Balance at 1 July 2021	77,003,347	(68,472,350)	450,686	-	8,981,683
Loss for the year	-	(8,620,588)	-	-	(8,620,588)
Total comprehensive loss for the year	-	(8,620,588)	-	-	(8,620,588)
Shares issued during the year	7,183,790	-	-	-	7,183,790
Share issue costs	(650,740)	-	-	-	(650,740)
Issue of options to employees	-	-	291,189	-	291,189
Issue of options to consultants	-	-	211,382	-	211,382
Issue of options to broker	-	-	141,160	-	141,160
Options lapsed during the period	-	68,425	(68,425)	-	-
Equity settled share-based payments	-	-	79,106	-	79,106
Balance at 30 June 2022	83,536,397	(77,024,513)	1,105,098	-	7,616,982

The above Statement of Changes in Equity should be read in conjunction with the accompanying notes.

Arovella Therapeutics Limited
Statement of Cash Flows
For the year ended 30 June 2022

	Consolidated	
Notes	2022	2021
	\$	\$
Cash flows from operating activities		
Receipts from customers	437,494	124,345
Payments to suppliers and employees	(7,048,845)	(4,756,985)
Interest paid	(15,259)	(25,869)
Government grants and tax incentives	524,042	1,115,540
Interest received	3,845	5,866
Finance costs	(169,522)	(7,425)
Net cash (outflow) from operating activities	(6,268,245)	(3,544,528)
Cash flows from investing activities		
Payments for property, plant and equipment	(35,026)	(166,107)
Payments for intangible assets	(530,972)	(348,447)
Net cash (outflow) from investing activities	(565,998)	(514,554)
Cash flows from financing activities		
Proceeds from issues of shares and other equity securities	6,256,211	9,856,391
Principal elements of lease payments	(68,199)	(57,583)
Net cash inflow from financing activities	6,188,012	9,798,808
Net (decrease)/ increase in cash and cash equivalents	(646,231)	5,739,726
Cash and cash equivalents at the beginning of the financial year	6,717,198	977,472
Cash and cash equivalents at the end of the financial year	6,070,967	6,717,198

The above Statement of Cash Flows should be read in conjunction with the accompanying notes.

Contents of the notes to the financial statements

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1 Summary of significant accounting policies

Basis of preparation

The preliminary final report is presented in Australian dollars and has been prepared on an accrual basis and is based on historical cost basis except for selected current and non-current assets which are measured at fair value at reporting date.

The preliminary final report has been prepared in accordance with Australian Securities Exchange Listing Rules as they relate to Appendix 4E and in accordance with the recognition with the recognition and measurement requirements of the Australian Accounting Standards (including Australian Accounting Interpretations) adopted by the AASB and the Corporations Act 2001.

As such, the preliminary final report does not include all notes of the type normally included within the annual financial report and therefore cannot be expected to provide a full understanding of the financial performance and financial position as the full financial report. It is recommended that the preliminary final report be considered together with any public announcements made by the Company in accordance with the continuous disclosure obligations of the Australian Securities Exchange Listing Rules.

(i) Going concern

The financial statements have been prepared on the going concern basis, which contemplates continuity of normal business activities and the realisation of assets and settlement of liabilities in the normal course of business. This includes the continued development and commercialisation of the Company's current projects.

As disclosed in the financial statements, the Company incurred a loss of \$8,620,588 (2021: \$5,047,465) and had operating cash outflows of \$6,268,245 for the year ended 30 June 2022 (2021: \$3,544,528). As at 30 June 2022, the Company's held cash and cash equivalents of \$6,070,967 (2021: \$6,717,198). The Directors are of the opinion that the Company is a going concern for the following reasons:

- The Directors anticipate that a further equity raising will be required and will be completed in FY2023.
- Based on prior experience, the Directors are confident that they can raise additional capital if and when required.

Should this equity raising not be completed, there is a material uncertainty that may cast significant doubt as to whether the Company will be available to realise its assets and extinguish its liabilities in the normal course of business. Despite these uncertainties, the Directors are of the view that the Company will be successful in the above matter and accordingly have adopted the going concern basis of the preparation of the financial report.

COVID-19 has led to widespread restrictions on both national and international travel. To date, the Company's supply chain has not been affected. Nevertheless, the risk that COVID-19 poses in terms of overwhelming health care systems must be taken into account when factoring in programs that are at the clinical stage.

As a result of the COVID-19 outbreak, or similar pandemics, the Company may experience disruptions that could severely impact the business in the following ways:

- delays or disruptions in supply chain for materials required for research and/or clinical trials;
- delays in the completion of research due to infection of key research personnel;
- delays enrolling patients into clinical trials;
- reduced ability to engage with the medical, pharmaceutical industry and investor communities due to the cancellation of conferences and travel bans, which may impact the ability to attract collaborators, potential industry partners and investors.

1 Summary of significant accounting policies (continued)

Basis of preparation (continued)

(ii) New and amended standards adopted by the Company

For the year ended 30 June 2022, the Company has adopted all of the new or amended Accounting Standards and Interpretations issued by the Australian Accounting Standards Board ('AASB') that are mandatory for the current reporting period.

The adoption of these standards has not had any impact on the disclosures or amounts reported in these financial statements.

New Standard and Interpretations in issue not yet adopted

The Directors have also reviewed all of the new and revised Standards and Interpretations in issue not yet adopted for the year ended 30 June 2022. As a result of this review the Directors have determined that there is no material impact of the Standards and Interpretations in issue not yet adopted on the Company and, therefore, no change is necessary to Company accounting policies.

(iv) Comparative figures

Comparative figures, are, where appropriate, reclassified to be comparable with figures presented in the current financial year.

2 Revenue and expenses

(a) Revenue from contracts with customers

	2022	2021
	\$	\$
Sales revenue from contracts with customers		
License and supply agreements and research and development projects	<u>295,810</u>	<u>257,347</u>

The Company derives its revenue from the sale of goods and the provision at services at a point in time and over time in the following major categories: (i) licence and supply agreements; and, (ii) research and development income. The Company has a balance of contract liabilities of \$341,684 for the year ended 30 June 2022 (2021: \$200,000).

	2022	2021
	\$	\$
<i>At a point in time</i>		
Licence and supply agreements	295,810	124,345
<i>Over time</i>		
Research and development income	-	133,002
Total revenue	<u>295,810</u>	<u>257,347</u>

(b) Other Income and Expenses

(i) Interest income

Interest income from a financial asset is recognised when it is probable that the economic benefits will flow to the Company and the amount of revenue can be reliably measured. Interest income is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that assets' net carrying amount on initial recognition.

2 Revenue and expenses (continued)

(b) Other Income and Expenses (continued)

	2022	2021
	\$	\$
Interest income	3,845	6,542
<i>(ii) Other income</i>		
	2022	2021
	\$	\$
R&D Tax Incentive*	-	632,370
COVID-19 assistance grant	-	174,300
Export Market Development Grants (EMDG)	-	100,000
	-	906,670

* R&D tax incentive

The Company's research and development (R&D) activities are eligible under an Australian government tax incentive for eligible expenditure. Management has assessed these activities and expenditure to determine which are likely to be eligible under the incentive scheme. Amounts are recognised when it has been established that the conditions of the tax incentive have been met and that the expected amount can be reliably measured. For the year ended 30 June 2022, the Company has not recognised any R&D tax incentive as the Company has applied for an Advance Overseas Findings for its cell therapy projects and the application is currently under review by AusIndustry. As the application has not been finalised as of the date of report, no amount has been recognised (2021: \$632,370).

(iii) Depreciation and amortisation

	2022	2021
	\$	\$
Depreciation	135,614	140,482
Depreciation charge of right-of-use assets	60,238	62,698
Amortisation	355,636	448,996
	551,488	652,176

(iv) Finance costs

	2022	2021
	\$	\$
Finance costs*	169,522	7,425
Interest expense	25,198	25,869
	194,720	33,294

* Finance cost in 2022 includes the interest expense paid to HC Berlin Pharma (HCBP) of \$169,462.

2 Revenue and expenses (continued)

(b) Other Income and Expenses (continued)

(v) Other expenses

	2022	2021
	\$	\$
<i>Other expenses</i>		
Write-off of inventories	-	21,801
Share-based payment expense	581,676	37,337
Legal fees	120,285	59,126
Consultant fees	444,597	444,321
Patent and trademark costs	382,888	281,612
General & Admin	889,438	583,915
Investor relation costs	277,341	211,913
Audit and accounting fees	252,685	266,456
Insurances	188,316	143,959
Travel costs	78,329	5,868
Total other expenses	3,215,555	2,056,308

3 Loss per share

(a) Basic and diluted loss per share

	2022	2021
	Cents	Cents
Basic and diluted loss per share	(1.57)	(1.52)

(b) Reconciliations of losses used in calculating loss per share

	2022	2021
	\$	\$
Loss for the year		
From continuing operations	(8,620,588)	(5,047,465)

The weighted average number of ordinary shares used in the calculation of basic loss per share and diluted loss per share is as follows:

Weighted average number of shares used as the denominator

	2022	2021
	Number	Number
Weighted average number of ordinary shares for the purpose of basic/diluted loss per share	549,623,838	330,893,281

4 Trade and other receivables

	2022	2021
	\$	\$
Trade receivables ⁽ⁱ⁾	36,290	9,595
R&D incentive receivable ⁽ⁱⁱ⁾	-	524,042
	36,290	533,637

(i) the average credit period on sales of goods and rendering of services is 60 days. All amounts are short term except when conditional on other party achieving a milestone. The carrying value of trade receivables is considered a reasonable approximation of fair value.

(ii) refer to Note 2(b) for explanation.

5 Intangible assets

	Patents	Development costs	Total
	\$	\$	\$
Year ended 30 June 2021			
Opening carrying value	132,358	4,118,864	4,251,222
Additions	-	348,447	348,447
Impairment	-	(1,239,467)	(1,239,467)
Amortisation	-	(448,996)	(448,996)
Closing net book amount	132,358	2,778,848	2,911,206
Year ended 30 June 2022			
Opening carrying value	132,358	2,778,848	2,911,206
Additions	-	530,972	530,972
Impairment	-	(833,271)	(833,271)
Amortisation	-	(355,636)	(355,636)
Closing net book amount	132,358	2,120,913	2,253,271

In the current year, the Company has decided not to commit further resources into the Sumatriptan project as the co-development opportunity with Strides was terminated. The carrying value of the Sumatriptan project at reporting date has been fully impaired resulting in an impairment expense of \$833,271 recognised in the statement of profit or loss and other comprehensive loss.

6 Trade and other payables

	2022	2021
	\$	\$
Current		
Trade payables (i)	751,909	227,459
Payroll tax and other statutory liabilities	-	4,412
Sundry payables and accrued expenses	63,616	472,876
Legal settlement (ii)	-	522,152
	815,525	1,226,899

(i) Trade payables are non-interest bearing and are normally settled on 30-45 day terms and include superannuation and PAYG.

(ii) Arovella entered into a settlement agreement with the receiver for HC Berlin Pharma (HCBP) in 2018. As of 30 June 2022, Arovella has paid €330,000 as the final settlement (2021: second payment made of €250,000).

7 Share capital

(a) Accounting policy - issued capital

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares or options are shown in equity as a deduction, net of tax, from the proceeds. Incremental costs directly attributable to the issue of new shares or options for the acquisition of a new business are not included in the cost of acquisition as part of the purchase consideration.

	2022	2022	2021	2021
	Shares	\$	Shares	\$
Ordinary shares				
Fully paid	669,835,226	83,536,397	480,819,986	77,003,347
	669,835,226	83,536,397	480,819,986	77,003,347
Total issued capital	669,835,226	83,536,397	480,819,986	77,003,347

Ordinary shares entitle the holder to participate in dividends and the proceeds on winding up of the Company in proportion to the number of and amounts paid on the shares held.

On a show of hands every holder of ordinary shares present at a meeting in person or by proxy, is entitled to one vote, and upon a poll each share is entitled to one vote.

Ordinary shares have no par value and the Company does not have a limited amount of authorised capital.

7 Share capital (continued)

Movements in ordinary shares on issue

Details	Number of shares	Total \$
Balance 1 July 2020	142,254,865	67,385,981
Share consolidation adjustment	(468)	-
Rights issue (August 2020)	142,254,397	3,556,360
Shares issue (August 2020)	21,338,159	533,455
Shares issue in lieu of cash (October 2020)	988,949	35,310
Shares issue (December 2020)	76,708,975	2,761,523
Shares issue (February 2021)	1,111,112	40,000
Shares issue (June 2021)	96,163,997	3,654,232
Less: Capital raising costs ¹	-	(963,514)
Balance 30 June 2021	480,819,986	77,003,347
Shares issue (November 2021)	100,894	5,045
Shares issue (February 2022)	120,230,220	4,568,748
Shares issue (March 2022)	52,842,026	2,007,997
Shares issue (March 2022)	4,210,522	160,000
Shares issue in lieu of cash (March 2022)	11,000,000	418,000
Shares issue (March 2022)	631,578	24,000
Less: Capital raising costs ²	-	(650,740)
Balance 30 June 2022	669,835,226	83,536,397

1. \$239,025 transaction costs on share issues related to the fair value of 9,132,603 unlisted options issued to external corporate advisory group Baker Young Stockbrokers for capital raise brokerage services and placement services rendered. Out of the total 9,132,603 unlisted options to Baker Young, 2,923,385 unlisted options are yet to be issued as they requires shareholders approval in the upcoming General Meeting.

2. \$141,160 transaction costs on share issues related to the fair value of 4,854,999 unlisted options issued to external corporate advisory group Baker Young Stockbrokers for capital raise brokerage services and placement services rendered.